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Ultrasound-indicated cerclage: Shirodkar vs. McDonald

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***Objective*: To compare the efficacy of Shirodkar to McDonald cerclage in patients with singleton pregnancies undergoing an ultrasound-indicated cerclage. *Methods*: Historical cohort of all patients with singleton pregnancies undergoing cerclage for the indication of a short cervix on ultrasound (ultrasound indicated) at one institution in 2005–2010. We compared outcomes based on cerclage type, Shirodkar or McDonald. Outcome measures were gestational age (GA) at delivery, delivery ≥35 weeks, ≥32 weeks, and PPROM. Multivariable regression analysis was performed to control for significant variables. *Results*: Seventy-four patients with singleton pregnancies underwent an ultrasound-indicated cerclage in the study period (47 Shirodkar, 27 McDonald). Shirodkar was associated with later GA at delivery (mean GA at delivery 36.98 +/− 3.39 vs. 33.34 +/− 6.37 weeks, p = 0.006), a higher likelihood of delivering ≥35 weeks (83 vs. 55.6%, p = 0.011) and ≥32 weeks (91.5 vs. 59.3%, p = 0.001), and a lower likelihood of preterm premature rupture of membrane (PPROM) (13.0 vs. 46.2%, p = 0.002). On adjusted analysis controlling for differing baseline characteristics, Shirodkar remained significantly associated with an increased incidence of delivery ≥32 weeks (odds ratio [OR]: 5.180, 95% CI: 1.024–26.205). *Conclusion*: Compared to the McDonald technique, the Shirodkar technique was more effective in prolonging pregnancy in patients with singleton pregnancies undergoing ultrasound-indicated cerclage. A prospective trial is needed to compare these two techniques.**

Keywords: Cerclage, Shirodkar, McDonald, preterm birth

Background

Cervical cerclage has been a common practice in obstetrics since it was first described by Shirodkar [1] and then McDonald [2] in the 1950's. Both types of cerclages have been placed because of a patient's obstetrical history, physical examination, ultrasound findings, or a combination of the above. In certain high-risk women, cerclage appears to prolong pregnancy and reduce the risk of preterm birth [3,4]. Regarding cerclage for patients with a short cervical length on ultrasound (ultrasound-indicated cerclage), randomized trials suggest that cerclage placement in this population is not effective in low-risk patients, but appears to prolong pregnancy in high-risk patients, such as those with a prior preterm birth or second trimester pregnancy loss [5–8].

The observational studies comparing the Shirodkar and McDonald techniques in all patients undergoing cerclage have yielded conflicting results [9–11]. The evidence regarding Shirodkar vs. McDonald cerclage specifically for ultrasound-indicated cerclage is limited to a large retrospective analysis of data from four prospective randomized trials comparing cerclage to expectant management in 277 patients with a short cervical length on ultrasound [12]. In this secondary analysis, the Shirodkar group delivered at a later mean gestational age (GA) (36.3 vs. 35.0 weeks, p = 0.02). The authors performed a regression analysis controlling for baseline cervical length and other relevant baseline characteristics and concluded that there was no difference in outcomes between the two cerclage types. Based on this and the lack of a prospective comparative trial, the choice of McDonald or Shirodkar cerclage is currently guided solely by the clinical experience, physician training, or decision of the operator. The objective of this study was to compare Shirodkar and McDonald ultrasound-indicated cerclage in a single institution.

Methods

After Institutional Review Board approval was obtained, we queried the Mount Sinai hospital database using ICD-9 codes for all cerclages performed over a 6-year period from January 2005 through December 2010. We also queried the labor and delivery log for possible missing cases. Any patient undergoing cervical cerclage for any indication was included in the initial chart review. The medical record was reviewed for patient history, indication for cerclage, cerclage type, perioperative treatments, hospital admissions, and delivery outcomes.

Cerclage indications were categorized as follows:

- History-indicated: any cerclage placed during pregnancy for the *sole* indication of prior obstetrical history, cervical trauma/surgery (such as cone biopsy), or multiple gestation.
- Ultrasound-indicated: any cerclage placed during pregnancy for the indication of a short cervical length on ultrasound.
- Physical-exam-indicated: any cerclage placed in a patient with a dilated cervix on exam or membranes visible at the external os on speculum examination. This included patients who were initially diagnosed with a short cervix on ultrasound, but were found to have prolapsed membranes at the time of cerclage placement.
- Abdominal cerclage: any cerclage placed abdominally either during pregnancy or between pregnancies.

We included all patients with singleton pregnancies who underwent an ultrasound-indicated cerclage.

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Since this is a retrospective analysis, the decision to perform a Shirodkar or McDonald cerclage, and decisions regarding pregnancy management were at the discretion of the obstetrician. However, in our institution, the techniques for each procedure are relatively uniform. McDonald cerclages are placed using 5-mm Mersilene suture circumferentially around the cervix counterclockwise from 11 o'clock. The knot is tied at 12 o'clock. Shirodkar cerclages are performed in a modified manner as described by Druzin and Berkely [13]. After the vaginal mucosa is dissected off of the cervix anteriorly and posteriorly, the lateral vaginal mucosa on each side of the cervix is grasped with curved Allis clamps and retracted laterally. A double needle 5-mm Mersilene suture is then passed from anterior to posterior on both the left and right side of the cervix in the space between the cervical stroma and the retracted vaginal mucosa. The knot is then tied at 6 o'clock. The anterior vaginal mucosa is routinely reapproximated. The Posterior vaginal mucosa is typically left open, unless sutures are needed for hemostasis. In our institution, cerclages are placed by house staff and attending physicians together.

We compared outcomes in patients with singleton pregnancies undergoing Shirodkar and McDonald ultrasound-indicated cerclage. Our primary outcomes were the likelihood of delivery ≥35 weeks, delivery ≥32 weeks, and preterm premature rupture of membranes (PPROM) with the cerclage in place. We did not compare the outcome of delivery ≥37 weeks (term birth) because the timing of routine cerclage removal is not uniform in our institution (typically between 36 and 39 weeks) and the GA at cerclage removal could influence timing of delivery. We also compared mean and median GA at delivery. For patients in whom the exact GA at delivery was unknown, if we knew they were still pregnant after 32 or 35 weeks (for example, if we had documentation that the cerclage was removed at 37 weeks), we included the patients for the categorical outcomes ≥35 and ≥32 weeks, but did not include them in the comparison for GA at delivery. Student's *t*-test, Mann-Whitney *U*, and χ^2 test were used when appropriate (SPSS for Windows 16.0, Chicago, IL, USA). A two-tailed *p*-value of ≤0.05 was considered significant. We performed a planned multivariable regression analysis controlling for significant baseline characteristics.

Results

Over the study period, there were 317 cerclages placed at our institution. Twenty-five patients had incomplete records (14 with no operative note, 11 who delivered elsewhere with no information in the medical record regarding delivery) precluding them from analysis. There were 94 ultrasound-indicated cerclages. After excluding the 20 twin pregnancies, there were 74 patients with singleton pregnancies who underwent ultrasound-indicated cerclage in the study period. Forty seven (63.5%) had a Shirodkar cerclage and 27 (36.5%) had a McDonald cerclage.

Baseline characteristics are shown in Table I. There were no significant differences between the groups except patients undergoing Shirodkar cerclage were significantly more likely to have a private attending physician, were less likely to be Hispanic, and more likely to be white. The mean cervical length at the time of cerclage placement was 14.29 and 14.52 mm, respectively. Risk factors for preterm birth were similar between the two groups (Table II). Of note, all patients were at increased risk for preterm birth and 69.6 and 65.4%, respectively, had a history of a prior preterm birth.

Pregnancy outcomes are shown in Table III. Compared to McDonald cerclage, Shirodkar cerclage was significantly associated with later GA at delivery, a higher proportion of women delivering ≥32 and ≥35 weeks, and less PPROM. On adjusted analysis controlling for maternal race and private attending physician, Shirodkar remained associated with a higher proportion of women delivering ≥32 weeks (OR: 5.180, 95% CI: 1.024–26.025).

Table I. Baseline characteristics in patients with singleton pregnancies undergoing ultrasound-indicated cerclage, based on cerclage type.

	Shirodkar (*n* = 47)	McDonald (*n* = 27)	*p*
Age	32.55 +/− 5.18	31.80 +/− 5.82	0.575
Gestational age at cerclage placement	19.56 +/− 2.57	19.22 +/− 2.53	0.580
BMI	28.05 +/− 6.93	28.80 +/− 5.61	0.763
Cervical length (mm)	14.29 +/− 6.07	14.52 +/− 6.51	0.884
Race			
White	60.9%	28%	0.013
African American	17.4%	20%	
Asian	6.5%	8.0%	
Hispanic	10.9%	44.0%	
Other	4.3%	0.0%	
Private attending physician	91.5%	37.0%	<0.001
Prior term birth	51.1%	48.1%	0.808

Table II. Risk factors for preterm birth in patients with singleton pregnancies undergoing ultrasound-indicated cerclage, based on cerclage type.

	Shirodkar (*n* = 47)	McDonald (*n* = 27)	*p*
Prior cone/leep	14.6%	24.0%	0.339
Mullerian anomaly (including resected septum)	11.0%	0%	0.232
Prior cerclage	26.1%	12.0%	0.165
Prior preterm birth or 16–24 week loss	69.6%	65.4%	0.715
Prior second trimester D&E	8.9%	0%	0.141

Discussion

In this retrospective study comparing McDonald and Shirodkar cerclage type for ultrasound-indicated cerclage, Shirodkar cerclage was associated with improved outcomes such as later GA at delivery, a greater proportion of women delivering ≥32 and ≥35 weeks, and less PPROM. On adjusted analysis controlling for baseline characteristics, Shirodkar remained significantly associated with a higher likelihood of delivery ≥32 weeks. This differs from the prior publication comparing Shirodkar and McDonald in ultrasound-indicated cerclage, which found no difference between the cerclage types [10]. In their study, Odibo et al. retrospectively analyzed the data from four prospective trials comparing cerclage to no cerclage in women with a short cervix. In three of the studies [14–16], the definition of a short cervical length was <25 mm and in each of these three studies a McDonald cerclage was used. In the fourth study [5], the definition of a short cervical length was ≤15 mm and a Shirodkar cerclage was used. Therefore, the comparison was between patients (in three studies) with a cervix <25 mm who received a McDonald cerclage and patients (in one study) with a cervical length ≤15 mm who received a Shirodkar cerclage. This can be seen in the difference in mean cervical length at baseline between their two groups (9.6 vs. 17 mm, p = 0.001). Despite the shorter cervical length in the Shirodkar group, the Shirodkar group delivered at a later

Table III. Pregnancy outcomes in patients with singleton pregnancies undergoing ultrasound-indicated cerclage, based on cerclage type.

	Shirodkar (n = 47)	McDonald (n = 27)	OR (95% CI)	p	Adjusted OR (95% CI)[a]
Gestational age at delivery (mean)	36.58 +/− 3.39	33.34 +/− 6.37		0.006	
Gestational age at delivery (median, 25%, 75%)	37.43 (35.93, 38.64)	36.0 (29.0, 38.86)		0.081	
Delivery ≥35 weeks	39 (83.0%)	15 (55.6%)	2.160 (1.234, 3.779)	0.011	2.154 (0.527, 8.810)
Delivery ≥32 weeks	43 (91.5%)	16 (59.3%)	2.704 (1.611, 4.538)	0.001	5.180 (1.024, 26.205)
PPROM	6 (13.0%)	12 (46.2%)	0.389 (0.223, 0.679)	0.002	0.410 (0..0930, 1.813)

OR, odds ratio; PPROM, preterm premature rupture of membranes.
[a]Adjusted for race and private attending physician.

mean GA (36.3 vs. 35.0 weeks, p = 0.02). The authors performed a regression analysis controlling for baseline cervical length and other baseline characteristics and found no difference in the rates of preterm birth <35, <32, and <28 weeks. Therefore they concluded that there was no difference in outcomes between the two cerclage types. Despite the regression analysis, the fact that the populations were quite heterogeneous (different institutions, different time, different entry criteria, different cervical length) limits their results and may explain the difference between their findings and ours, as our study was performed in one institution.

Another difference between the Odibo et al. study and ours is the baseline risk of the populations. In Odibo et al., the study was primarily in low-risk patients who were incidentally found to have a short cervix on ultrasound. Our study, however, was in high-risk patients. All patients had a risk factor for preterm birth and nearly two-thirds of all patients had a prior preterm birth or second trimester loss. This is not unexpected as routine cervical lengths in singleton pregnancies were not performed in our institution over the study period. Therefore, any patient undergoing a cervical length assessment would have to have been considered at increased risk for preterm birth in order to have undergone the cervical length assessment. Considering that cerclage appears to offer no or minimal benefit to low-risk women with a short cervical length on ultrasound [5,6], it follows that the type of cerclage placed would not matter either. However, in a high-risk population, such as ours, in which ultrasound-indicated cerclage appears to be beneficial [6–8], the type of cerclage may matter as well. Therefore, the difference in baseline risk between the populations may also explain the difference between our findings and those of Odibo et al. This may be similar to the studies regarding cerclage type (not specifically ultrasound-indicated), where overall there was no difference in outcomes, except in a high-risk subgroup, namely those with a prior cerclage, in which women with a Shirodkar delivered larger neonates [9]. A larger prospective randomized trial would be the best way to compare the two cerclage types in high risk, singleton pregnancies.

Our study is limited by its retrospective nature. Although we controlled for significant baseline characteristics, it is possible that other unmeasured baseline differences contributed to the difference in outcomes. Also, since the perioperative and pregnancy management was not standardized, differences in management may have contributed to the difference in outcomes as well. Only a prospective randomized trial could properly address this question. In the current environment of one retrospective study showing no difference in outcomes [12], the impetus for a prospective trial will remain low. However, the data in our study indicate that in fact a large, randomized, prospective trial is needed to compare Shirodkar and McDonald cerclage in high-risk singleton pregnancies with a short cervix. If our findings are confirmed in a prospective trial, performing Shirodkar cerclages could significantly reduce the risk of preterm birth in certain high-risk patients. This would also require a shift in the cerclage training paradigm in residency.

Declaration of Interest: The authors report no conflicts of interest.

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